Steroids, Topical
Therapeutic Class Review (TCR)

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FDA-APPROVED INDICATIONS

Drug	Manufacturer	Indications
Low Potency		
alclometasone dipropionate (Aclovate®)[1]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
desonide (Desonate®)[2]	Bayer	Treatment of mild to moderate atopic dermatitis
desonide (Desowen®)[3]	generic, Galderma	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
desonide (Verdeso™)[4]	Aqua	Treatment of mild to moderate atopic dermatitis
fluocinolone acetonide (Capex® Shampoo)[5]	Galderma	Treatment of seborrheic dermatitis of the scalp
fluocinolone acetonide (Derma-Smoothe/FS®)[6]	generic, Royal	Body oil: treatment of atopic dermatitis in adults; moderate to severe atopic dermatitis in patients 3 months and older for up to 4 weeks Scalp oil: treatment of psoriasis of the scalp in adult patients
fluocinolone acetonide (Synalar®)[7]	generic, Medimetriks	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
fluocinolone acetonide/urea* (NoxiPak Kit)[8]	Solutech	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
hydrocortisone (Ala-Cort®, Ala-Scalp®, Aqua Glycolic HC®, Dermasorb™ HC, MiCort™ HC, Scalacort®, Scalacort-DK® Kit, Texacort®, Pediaderm™ HC, Pediaderm™ TA)[9,10,11,12,13,14]	generic, Avidas, Arbor, Crown Labs, Mission, Sebela	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
Medium Potency		
betamethasone valerate (Luxiq®)[15]	generic, Prestium	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp
betamethasone valerate[16]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
clocortolone pivalate (Cloderm®)[17]	generic, Promius	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
fluocinolone acetonide (Synalar®)[18]	generic, Medimetriks	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
fluocinolone acetonide/Cetaphil cleanser lotion** (Xilapak Kit)[19]	Solutech	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
flurandrenolide (Cordran®)[20,21]	generic, Aqua	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
flurandrenolide (Cordran® Tape)[22]	Actavis	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
fluticasone propionate (Cutivate®)[23]	generic	Cream, Ointment: Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and atopic dermatitis Lotion: Relief of the inflammatory and pruritic manifestations of atopic dermatitis in patients 3 months of age and older

FDA-Approved Indications (continued)

Drug	Manufacturer	Indications
Medium Potency *(continued)*		
hydrocortisone butyrate (Locoid® / Lipocream)[24]	generic, Valeant	Treatment of mild to moderate atopic dermatitis in patients 3 months to 18 years of age
hydrocortisone probutate (Pandel®)[25]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age and older
hydrocortisone valerate (Westcort®)[26]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adult patients
mometasone furoate (Elocon®)[27]	generic, Merck	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 2 years of age or older
prednicarbate (Dermatop®)[28]	generic, Valeant	Relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses
High Potency		
amcinonide[29]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Sernivo topical spray: Only approved for treatment of mild to moderate plaque psoriasis in patients 18 years of age or older Topicort topical spray: Only approved for treatment of plaque psoriasis in patients 18 years of age or older
betamethasone dipropionate[30]	generic	
betamethasone dipropionate (Sernivo™)[31]	Promius	
betamethasone dipropionate augmented (Diprolene® AF)[32]	generic, Merck	
desoximetasone (Topicort®, Topicort® topical spray)[33,34]	generic, Taro	
fluocinonide[35]	generic	
fluocinonide (Vanos™)[36]	Medicis	
halcinonide (Halog®)[37]	Ranbaxy	
triamcinolone acetonide (Dermasorb™ TA, Kenalog®, Trianex™,Triderm®)[38,39,40,41]	generic, Ranbaxy, Crown Labs, Upsher-Smith	
triamcinolone acetonide/dimethicone (DermacinRx® SilaPak)[42]	generic, PureTek	
triamcinolone acetonide/silicone (DermacinRx® Silazone™)[43]	generic, PureTek	
triamcinolone acetonide/silicone (Silazone-II™)[44]	generic, PureTek	

FDA-Approved Indications (continued)

Drug	Manufacturer	Indications
Very High Potency		
clobetasol propionate (Clobex®, Clodan™ shampoo)[45, 46]	generic, Galderma	Lotion: Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Shampoo: Treatment of moderate to severe forms of scalp psoriasis Spray: Treatment of moderate to severe plaque psoriasis affecting up to 20% of body surface area
clobetasol propionate (Cormax®, Temovate/Temovate E®)[47,48,49]	generic, ECR Pharmaceuticals	Cream, gel, ointment: Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Solution: Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp
diflorasone diacetate (Apexicon E, Psorcon) [50]	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
clobetasol propionate (Olux®, Olux-E®)[51]	generic, Prestium	Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp and short-term treatment of mild to moderate plaque psoriasis of non-scalp regions
halobetasol propionate cream, ointment (Ultravate®)[52]	generic, Ranbaxy	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
halobetasol propionate (lotion) (Ultravate)[53]	Ranbaxy	Topical treatment of plaque psoriasis in adults
halobetasol propionate (Ultravate® X)[54]	generic, Ranbaxy	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

*Urea 20% cream is co-packaged with fluocinolone acetonide 0.01% as part of the NoxiPak Kit. It is used as a keratolytic.

**Cetaphil cleanser lotion is co-packaged with fluocinolone acetonide 0.01% as part of the Xilapak Kit. It is used as a cleanser.

OVERVIEW

Topical corticosteroids are used for a variety of inflammatory skin conditions.

Atopic dermatitis (AD) is a chronic, inflammatory dermatologic condition. The skin becomes pruritic and inflamed, causing swelling, cracking, weeping, crusting, and scaling. AD is often referred to as "eczema." It commonly occurs in patients affected by asthma and/or allergic rhinitis and is associated with elevated serum IgE levels. Usually diagnosed before the age of 5 years, AD can occur at any age, but occurs most frequently in children.[55]

Psoriasis is another inflammatory skin condition. Plaque psoriasis is the most common type which appears as patches of raised, reddish skin covered by silvery-white scale. These patches, or plaques, frequently form on the elbows, knees, lower back, and scalp. Controlling the signs and symptoms typically requires lifelong therapy.[56,57]

Seborrheic dermatitis is an inflammatory disorder affecting areas of the head and trunk, where sebaceous glands are most prominent. Scalp seborrhea varies from mild dandruff to dense scale, while facial and trunk seborrhea is characterized by powdery or greasy scale in skin folds and along hair margins.[58]

Pharmacotherapy choices for these conditions typically include emollients and topical corticosteroids.[59] Emollients remain the cornerstone of any AD pharmacotherapeutic regimen; they restore the skin barrier function. Topical corticosteroids are the standard of care to which other treatments are compared. The selected medication and potency should depend on medication efficacy then severity of disease, location and surface area of affected skin, intended duration of treatment, medication vehicle, patient preference, and the age of the patient. In short-term durations of treatment, high potency medications have greater efficacy when compared to less potent medications. However, highly potent topical corticosteroids do have an increased risk in side effects. Dermatologic effects, such as striae, atrophy, and tachyphylaxis, as well as potential non-dermatologic effects on linear growth rate, bone density, and hypothalamic-pituitary-adrenal (HPA) axis suppression, limit the long-term use of these agents. Additionally, the increased incidences of adverse dermatologic effects are positively correlated with the medication's frequency and duration of use. The true efficacy and risk of long-term topical corticosteroid use is unknown due to most clinical trials only involving short-term studies. Furthermore, it is recommended in the guidelines of care from the American Academy of Dermatology that continued therapy be supervised by the prescriber and, once a clinical response is demonstrated, a gradual reduction in utilization is appropriate.[60] Non-pharmacologic therapies, such as irritant avoidance and dietary intervention, have also been recommended, but these measures have not demonstrated consistent, beneficial results.

PHARMACOLOGY[61]

Topical corticosteroids mimic compounds that are secreted by the adrenal cortex. Their anti-inflammatory, antipruritic, and vasoconstrictive effects make them effective treatments in dermatological conditions. The exact mechanisms of action for the topical corticosteroids are not completely understood. Corticosteroids are thought to induce phospholipase A2 inhibitory proteins, or lipocortins, which control the biosynthesis of mediators of inflammation, such as prostaglandins and leukotrienes, by inhibiting the release of arachidonic acid. Substitution of a fluorine atom, an acetonide group, omission of the hydroxyl group, or esterification of a hydroxyl group in certain positions on the cortisol molecule increases anti-inflammatory activity. Based on this, corticosteroids are classified by potency. In this review, low, medium, high, and very high classifications are used to differentiate among the corticosteroids.

PHARMACOKINETICS[62]

The extent of topical absorption of corticosteroids is dependent on factors such as drug vehicle, skin integrity, use of occlusive dressings, use of more potent corticosteroids, use over large areas, and prolonged use. Areas where the stratum corneum is thin, such as the eyelids, genitalia, and face, also increase the risk for further absorption. The presence of skin disease processes, such as inflammation, may increase cutaneous absorption. Systemically absorbed corticosteroids are metabolized in the liver primarily, and excreted by the kidneys. Some corticosteroids and their metabolites are excreted into the bile.

CONTRAINDICATIONS/WARNINGS[63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98]

Corticosteroids are contraindicated in patients who have known hypersensitivities to any active or inactive ingredient in their prescribed preparation.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome (high blood levels of cortisol), hyperglycemia, glucosuria, and growth retardation in children can result from the systemic absorption of topical corticosteroids. If these effects are seen, the medications should be discontinued, applied less frequently, or substituted for a less potent topical corticosteroid. Patients who apply corticosteroids to a large surface area should periodically be evaluated by cortisol or ACTH stimulation tests. Recovery of the HPA axis is generally prompt and complete upon discontinuation of the corticosteroid.

Topical corticosteroids should not be used in the treatment of rosacea or perioral dermatitis. They also should not be used on the face, groin, or in the axillae because those areas are more prone to atrophic changes during corticosteroid therapy. Increased intraocular pressure, cataracts, and glaucoma have been reported in patients who use topical corticosteroids near the eyes. Topical corticosteroids should be discontinued if irritation develops.

Allergic contact dermatitis may occur with corticosteroids.

Fluocinolone acetonide (Derma-Smoothe/FS) contains 48% refined peanut oil NF and should be used with caution in peanut-sensitive patients. Therapy should be immediately discontinued if signs of hypersensitivity are present, or disease exacerbations occur.

DRUG INTERACTIONS[99]

When appropriate, antifungals or antibacterials should be applied to dermatological infections. If a response is not seen in a reasonable amount of time, specific to the drug being used, the topical corticosteroid should be discontinued until the infection is controlled.

ADVERSE EFFECTS[100,101,102,103,104,105,106,107,108,109,110,111,112,113,114,115,116,117,118,119,120,121,122,123,124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148]

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Low Potency					
alclometasone dipropionate (Aclovate)	1-2	2	nr	1-2	2
desonide (Desonate)	1	nr	nr	<1	nr
desonide (Desowen)	reported	nr	nr	reported	reported
desonide (Verdeso)	3	nr	nr	nr	reported
fluocinolone acetonide (Capex Shampoo)	nr	nr	nr	nr	nr
fluocinolone acetonide (Derma-Smoothe/FS)	5 (body oil) 5.2 (scalp oil)	nr	2 (body oil) 1.7 (scalp oil)	5 (body oil) 5.2 (scalp oil)	5 (body oil) 5.2 (scalp oil)
fluocinolone acetonide (Synalar, NoxiPak Kit, Xilapak Kit)	reported	reported	reported	reported	reported
hydrocortisone (Ala-Cort, Ala-Scalp, Aqua Glycolic HC, Dermasorb HC, MiCort HC, Scalacort, Scalacort-DK Kit, Texacort, Pediaderm HC, Pediaderm TA)	reported	reported	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Adverse effects (continued)

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Medium Potency					
betamethasone valerate (Luxiq)	2-44	reported	reported	2-44	reported
betamethasone valerate	reported	reported	reported	reported	reported
clocortolone pivalate (Cloderm)	reported	reported	reported	reported	reported
fluocinolone acetonide(Synalar)	reported	reported	reported	reported	reported
flurandrenolide (Cordran)	reported	reported	reported	reported	reported
flurandrenolide (Cordran Tape)	reported	reported	reported	reported	reported
fluticasone propionate (Cutivate)	0.6-2	0.5-7	0.5-1	1-2.9	1-2.9
hydrocortisone butyrate (Locoid / Lipocream)	nr	nr	nr	2	1
hydrocortisone probutate (Pandel)	<1	reported	reported	reported	reported
hydrocortisone valerate (Westcort)	reported	2	reported	2-6	1
mometasone furoate (Elocon)	1.6	nr	nr	1.6	nr
prednicarbate (Dermatop)	reported	reported	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
High Potency					
amcinonide	reported	reported	reported	reported	reported
betamethasone dipropionate	reported	reported	reported	reported	reported
betamethasone dipropionate (Sernivo)	4.5	reported	<1	6	reported
betamethasone dipropionate augmented (Diprolene AF)	reported	reported	<1	<1	reported
desoximetasone (Topicort)	<1	reported	<1	reported	reported
desoximetasone (Topicort Topical Spray)	nr	2.7	<1	2	2.7
fluocinonide	nr	nr	reported	reported	nr
fluocinonide (Vanos)	1.8-2.3	reported	nr	reported	reported
halcinonide (Halog)	nr	nr	nr	nr	nr
triamcinolone acetonide (Dermasorb TA, Kenalog, Trianex, Triderm)	reported	reported	reported	reported	reported
triamcinolone acetonide/dimethicone (DermacinRx SilaPak)	reported	reported	reported	reported	reported
triamcinolone acetonide/silicone (DermacinRx Silazone, Silazone-II)	reported	reported	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Adverse Effects (continued)

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Very High Potency					
clobetasol propionate (Clobex)	reported; 40 (spray)	1-2	reported	0.5-3	1
clobetasol propionate (Clodan shampoo)	reported	reported	reported	reported	reported
clobetasol propionate (Cormax, Temovate/Temovate E)	0.5-10	reported	<2	<2	<2
clobetasol propionate (Olux , Olux-E)	10	<1	nr	<2	<2
diflorasone diacetate (Apexicon E, Psorcon)	nr	nr	nr	nr	nr
halobetasol propionate (Ultravate, Ultravate X)	1.6-4.4	reported	reported	4.4	nr

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Local adverse effects occur more frequently with the use of occlusive dressings.

Adverse effects that are reported with the general use of topical corticosteroids and may occur more frequently with the use of occlusive dressings also include burning, itching, irritation, dryness, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, hypertrichosis, acneiform eruptions, hypopigmentation, secondary infection, skin atrophy, striae, and miliaria. While product-specific adverse event rates may not be available, these events are known to occur with topical corticosteroids.

Corticosteroids in gel formulations can cause dryness and irritation to the skin. Their use is usually limited to the scalp and beard areas.

SPECIAL POPULATIONS[149,150,151,152,153,154,155,156,157,158,159,160,161,162,163,164,165,166,167,168,169,170,171,172,173,174,175,176,177,178,179,180,181,182,183]

Pediatrics

Pediatric patients may be susceptible to higher incidences of corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and increased intracranial pressure because of a larger skin surface area: body weight ratio.

Pediatric Age	Drug
> 3 months	desonide (Desonate, Verdeso); fluocinolone acetonide (Derma-Smoothe/FS body oil); fluticasone (Cutivate) cream/lotion; hydrocortisone butyrate (Locoid/ Lipocream)
≥ 1 year	alclometasone (Aclovate)
≥ 2 years	mometasone (Elocon)
≥ 12 years	fluocinonide (Vanos); halobetasol (Ultravate cream, ointment); clobetasol (Temovate, Olux, Cormax)
≥ 13 years	betamethasone dipropionate (Diprolene AF)

Safety and efficacy of mometasone furoate 0.1% cream in children (greater than 2 years old) beyond 3 weeks have not been established. Clocortolone (Cloderm), desoximetasone (Topicort, Topicort Topical Spray), flurandrenolide (Cordran and tape), triamcinolone acetonide/dimethicone (DermacinRx Silapak), and triamcinolone acetonide/silicone (DermacinRx Silazone, Silazone-II) use in pediatrics should be limited to the least amount compatible with an effective therapeutic regimen. Hydrocortisone butyrate (Locoid/Lipocream) is not approved for pediatric use with the corticosteroid-dermatoses indication. The safety and effectiveness of all other products have not been established in pediatric patients.

A randomized, double-blind study compared the efficacy of hydrocortisone butyrate 0.1% cream with hydrocortisone 1% cream in 40 children suffering from atopic dermatitis.[184] The medications were applied twice daily for a maximum of 4 weeks. Complete clearance of skin symptoms was found in 36% of the hydrocortisone butyrate patients and in 23% of the hydrocortisone patients following 2 weeks of therapy and in 60 and 30%, respectively, after 4 weeks of treatment, a statistically significant difference. No serious adverse events were reported during the study.

Two randomized, parallel-group, double-blind studies in children ages 2 to 14 years old evaluated fluticasone propionate 0.05% cream with either hydrocortisone 1% cream (n=137) or hydrocortisone butyrate 0.1% cream (n=129) for both acute and maintenance treatment of moderate to severe atopic dermatitis.[185] Treatments were applied twice daily for 2 to 4 weeks, and thereafter as needed for up to 12 weeks. The primary outcome measure, Total Atopic Dermatitis Score, showed improvement in disease severity following treatment with fluticasone propionate compared with either hydrocortisone or hydrocortisone butyrate for acute treatment ($p<0.001$ versus hydrocortisone; $p=0.042$ versus hydrocortisone butyrate) and maintenance treatment ($p=0.006$ versus hydrocortisone; $p=0.042$ versus hydrocortisone butyrate). In both studies, treatments were equally well tolerated with no visible signs of skin atrophy.

In a double-blind, parallel-group trial, alclometasone dipropionate 0.05% cream or hydrocortisone butyrate 0.1% cream were applied twice daily for 2 weeks to 40 children (5 to 11 years old) with atopic dermatitis.[186] Improvement in erythema, induration, and pruritus averaged 76% for alclometasone dipropionate and 70% for hydrocortisone butyrate. Two patients in the alclometasone dipropionate group and 1 in the hydrocortisone butyrate group reported mild stinging.

Pregnancy

All topical corticosteroid products are Pregnancy Category C. Ultravate lotion has not been assigned a Pregnancy Category, but there are no data on topical halobetasol propionate in pregnant women.

DOSAGES[187,188,189,190,191,192,193,194,195,196,197,198,199,200,201,202,203,204,205,206,207,208,209,210,211,212,213,214,215,216,217,218,219,220,221,222,223,224,225,226]

Drug	Dose	Dosage Forms
Low Potency		
alclometasone dipropionate (Aclovate)	Apply to affected skin 2 or 3 times daily; treatment should be limited to 3 weeks	0.05% cream, ointment
desonide (Desonate)	Apply to affected skin twice daily; treatment should not exceed 4 weeks (Verdeso, Desonate) Desonide cream and ointment can be applied 2 to 4 times daily and the lotion can be applied 2 to 3 times daily	0.05% gel
desonide (Desowen)		0.05% cream, lotion, ointment
desonide (Verdeso)		0.05% foam
fluocinolone acetonide (Capex Shampoo)	Apply 1 ounce to scalp daily for 5 minutes, then rinse	0.01% shampoo
fluocinolone acetonide (Derma-Smoothe/FS)	Body oil: Adults: Apply thin film to the affected areas 3 times daily Pediatric: Apply thin film to moistened skin twice daily for up to 4 weeks Scalp oil: Dampen hair and then apply to scalp and cover overnight or a minimum of 4 hours before washing off	0.01% body oil, scalp oil
fluocinolone acetonide (Synalar)	Applied to the affected skin as a thin film from 2 to 4 times daily depending on the severity of the condition.	0.01% solution 0.01% solution kit (60 mL fluocinolone acetonide 0.01% topical solution and 454 grams Rehyla® Hair & Body Cleanser) (Synalar Solution Kit)
fluocinolone acetonide (XilaPak Kit)	Apply cleanser lotion to the affected area followed by fluocinolone acetonide solution and rub into skin until completely absorbed; then cover with silicone tape Apply twice daily or as directed by a physician	60 mL of 0.01% topical solution co-packaged with 4 oz of Cetaphil® cleanser lotion and silicone tape
fluocinolone acetonide/urea (NoxiPak Kit)	Apply fluocinolone to the affected area and rub into skin until completely absorbed; then apply urea cream and rub into skin until completely absorbed; then cover with silicone tape Apply twice daily or as directed by a physician	60 mL of 0.01% topical solution co-packaged with 85 g of 20% urea cream and silicone tape
hydrocortisone (Ala-Cort, Ala-Scalp, Aqua Glycol HC, Dermasorb HC, MiCort HC, Scalacort, Scalacort-DK Kit, Texacort, Pediaderm HC Complete Kit, Pediaderm TA)	Apply to affected skin 2 to 4 times daily Cleansing Shampoo: Massage moderate amount into a wet scalp and leave on scalp 2 to 3 minutes or apply liberally to all areas of the body and lather; then rinse thoroughly	0.25% lotion 0.5% cream, ointment 1% cream, gel, lotion, ointment, solution 2% gel, lotion 2% lotion and cleansing shampoo kit 2.5% cream, lotion, ointment, solution Pediaderm HC 2% Complete Kit comes with protective emollient lotion tube

Dosages (continued)

Drug	Dose	Dosage Forms
Medium Potency		
betamethasone valerate (Luxiq)	Apply to scalp twice daily; occlusive dressings should not be used unless directed by physician	0.12% foam
betamethasone valerate	Apply to affected skin 2 to 4 times daily	0.1% cream, lotion, ointment
clocortolone pivalate (Cloderm)	Apply to affected skin 3 times daily	0.1% cream
fluocinolone acetonide (Synalar)	Apply to affected skin 2 to 4 times daily	0.025% cream, ointment, cream kit (120 grams fluocinolone acetonide 0.025% topical cream and 255 grams Keradan™ Cream) (Synalar Cream Kit), ointment kit (120 grams fluocinolone acetonide 0.025% topical ointment and 255 grams Keradan™ Cream) (Synalar Ointment Kit)
flurandrenolide (Cordran)	Apply to affected skin 2 to 3 times daily	0.05% lotion 0.05% cream 0.05% ointment
flurandrenolide (Cordran Tape)	Apply tape to affected skin every 12 to 24 hours	4 mcg/cm^2 tape
fluticasone propionate (Cutivate)	Ointment: Apply to affected skin twice daily Cream: Apply to affected skin once or twice daily Lotion: Apply to affected skin once daily Treatment should be limited to 4 weeks	0.005% ointment 0.05% cream 0.05% lotion
hydrocortisone butyrate (Locoid / Lipocream)	Apply to affected skin 2 to 3 times daily; treatment should be limited to 2 weeks	0.1% cream, solution, ointment, lotion
hydrocortisone probutate (Pandel)	Apply to affected skin once or twice daily; if no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary	0.1% cream
hydrocortisone valerate (Westcort)	Apply to affected skin 2 to 3 times daily; occlusive dressings should not be used unless directed by a physician	0.2% ointment 0.2% cream (generic only)
mometasone furoate (Elocon)	Apply to affected skin once daily; treatment should be limited to 3 weeks	0.1% cream, lotion, ointment
prednicarbate (Dermatop)	Apply to affected skin twice daily	0.1% cream (emollient), ointment

Dosages (continued)

Drug	Dose	Dosage Forms
High Potency		
amcinonide	Apply to affected skin 2 to 3 times daily	0.1% cream, lotion, ointment
betamethasone dipropionate	Apply to affected skin once to twice daily	0.05% cream, lotion, ointment
betamethasone dipropionate (Sernivo)	Apply to affected skin twice daily; treatment beyond 4 weeks is not recommended	0.05% spray
betamethasone dipropionate augmented (Diprolene AF)	Apply to affected skin once or twice daily; total dose should not exceed 50 g or mL per week; treatment should be limited to 2 weeks; occlusive dressings should not be used	0.05% cream, gel, lotion, ointment
desoximetasone (Topicort)	Apply to affected skin twice daily	0.05% cream, gel, ointment 0.25% cream, ointment
desoximetasone (Topicort Topical Spray)	Plaque psoriasis: apply as a thin film to the affected skin twice daily; rub in gently; occlusive dressings should not be used unless directed by a physician. Treatment beyond 4 weeks is not recommended.	0.25% spray
fluocinonide	Apply to affected skin 1 to 4 times daily	0.05% cream, gel, ointment, solution
fluocinonide (Vanos)	Apply to affected skin once or twice daily; total dose should not exceed 60 g per week; treatment should be limited to 2 weeks	0.1% cream
halcinonide (Halog)	Apply to affected skin 1 to 3 times daily	0.1% cream, ointment
triamcinolone acetonide (Dermasorb TA, Kenalog, Trianex, Triderm,	Apply to affected skin 2 to 4 times daily Apply to affected skin 2 to 3 times daily (Dermasorb TA and Triderm)	0.025% cream, lotion, ointment 0.05% Trianex ointment 0.1% cream, lotion, ointment 0.1% cream and emollient cream kit 0.5% cream, ointment 0.147 gm/1 gm topical spray
triamcinolone acetonide/ dimethicone (DermacinRx SilaPak)	Apply triamcinolone acetonide to affected area 2 to 3 times daily, depending on severity; Apply dimethicone cream liberally as needed; silicone tape to be applied to wound or scar as needed or as directed by physician; Tape to be removed, area washed, and new tape applied at least every 24 hours	0.1% Kit (80 gm of 0.1% triamcinolone acetonide cream, 118mL of 5% dimethicone, 1 roll silicone tape)
triamcinolone acetonide/ silicone (DermacinRx Silazone)	Apply triamcinolone acetonide to affected area 2 to 3 times daily, depending on severity; Apply silicone (Silazone) sheet for 4 to 8 hours to ensure no adverse reactions; if none, apply to clean skin nightly and remove each morning (replace weekly); Continue using silicone for approximately 3 to 6 months as directed	0.1% Kit (80 gm of 0.1% triamcinolone acetonide cream, silicone gel sheet: 5 per kit)
triamcinolone acetonide/ silicone (Silazone-II)	Apply triamcinolone acetonide to affected area 2 to 3 times daily, depending on severity; Apply silicone (Silazone) sheet for 4 to 8 hours to ensure no adverse reactions; if none, apply to clean skin nightly and remove each morning (replace weekly); Continue using silicone for approximately 3 to 6 months as directed	0.1% Kit (80 gm of 0.1% triamcinolone acetonide cream, silicone gel sheet: 3 per kit)

Dosages (continued)

Drug	Dose	Dosage Forms
Very High Potency		
clobetasol propionate (Clobex, Clodan shampoo)	Apply lotion or spray to affected skin twice daily; total dose should not exceed 50 g or 1.75 ounces per week; treatment should be limited to 2 weeks (4 weeks for moderate to severe plaque psoriasis); apply shampoo to dry scalp once daily and rinse after 15 minutes	0.05% lotion, shampoo, spray Clodan Kit contains (clobetasol propionate [Clodan] 0.05% shampoo and Rehyla® Hair & Body Cleanser)
clobetasol propionate (Cormax, Temovate/Temovate E)	Apply to affected skin twice daily; total dose should not exceed 50 g or mL per week; treatment should be limited to 2 weeks	0.05% cream, gel, ointment, solution 0.05% cream (Temovate E)
clobetasol propionate (Olux/Olux-E)	Apply to affected skin twice daily; total dose should not exceed 50 g per week; treatment should be limited to 2 weeks	0.05% foam
diflorasone diacetate (Apexicon E, Psorcon)	Apply to affected skin twice daily	0.05% cream, ointment
halobetasol propionate (Ultravate)	Cream, Ointment: Apply to affected skin once or twice daily; Lotion: Apply a thin layer to affected areas twice daily Total dose for any formulation should not exceed 50 g per week; treatment should be limited to 2 weeks; occlusive dressings should not be used	0.05% cream, ointment, lotion
halobetasol propionate (Ultravate X)	Apply to affected skin once or twice daily; total dose should not exceed 50 g per week; treatment should be limited to 2 weeks; occlusive dressings should not be used	Ultravate X 0.05% cream, ointment (packaged with a tube of 10% ammonium lactate topical cream)

Once atopic dermatitis is stabilized with daily treatment, studies have shown that intermittent therapy with more potent topical corticosteroids can be as effective as daily therapy with a mild topical corticosteroid.[227,228] During intermittent treatment, use of emollients is recommended on days that steroids are not applied.

CLINICAL TRIALS

Search Strategy

Articles were identified through searches performed on PubMed and review of information sent by manufacturers. Search strategy included the FDA-approved use of all drugs in this class. Randomized, controlled, comparative trials are considered the most relevant in this category. Studies included for analysis in the review were published in English, performed with human participants, and randomly allocated participants to comparison groups. In addition, studies must contain clearly stated, predetermined outcome measure(s) of known or probable clinical importance, use data analysis techniques consistent with the study question, and include follow-up (endpoint assessment) of at least 80% of participants entering the investigation. Despite some inherent bias found in all studies including those sponsored and/or funded by pharmaceutical manufacturers, the studies in this therapeutic class review were determined to have results or conclusions that do not suggest systematic error in their experimental study design. While the potential influence of manufacturer sponsorship and/or funding must be considered, the studies in this review have also been evaluated for validity and importance.

clobetasol propionate (Cormax, Temovate) and betamethasone dipropionate (Diprolene)

A double-blind study compared the effectiveness of clobetasol propionate 0.05% ointment and betamethasone dipropionate 0.05% ointment twice daily in 130 patients with moderate to severe signs of psoriasis for 2 weeks.[229] Both drugs were well tolerated. Significantly more patients showed greater improvement when treated with clobetasol propionate. Follow-up evaluation 2 weeks after the treatment period showed longer remissions with clobetasol propionate use ($p<0.001$).

fluocinolone acetonide (Synalar) and betamethasone dipropionate (Diprolene)

In a double-blind, randomized study, 62 patients with psoriasis or eczema were treated with betamethasone dipropionate 0.05% cream or fluocinolone acetonide 0.025% cream twice daily for 3 weeks.[230] Both preparations were effective, well tolerated, and cosmetically acceptable. Of the patients treated with betamethasone dipropionate, 57%were rated as being “much better” in the overall assessment of response at the end of the trial period compared to only 25% of fluocinolone acetonide patients.

fluticasone propionate (Cutivate) and betamethasone dipropionate (Diprolene)

A randomized, double-blind, parallel-group study compared the safety, tolerability, and efficacy of fluticasone propionate 0.005% ointment and betamethasone dipropionate 0.05% ointment twice daily in 92 patients with moderate to severe eczema.[231] Statistically significant improvement in the severity of signs and symptoms was found as early as 2 weeks following treatment initiation in both groups. There was no significant difference between the treatments following 2 or 4 weeks of therapy with regard to almost all efficacy variables. Both treatments were well tolerated and showed minimal suppression of the hypothalamic-pituitary-adrenal (HPA) axis as evidenced by morning plasma cortisol concentration determinations.

The efficacy, safety, and tolerability of fluticasone propionate 0.005% ointment and betamethasone dipropionate 0.05% ointment were compared in a 12-week, randomized, double-blind, parallel-group

study of 74 patients with moderate to severe psoriasis.[232] Fluticasone propionate was not significantly different from betamethasone dipropionate at day 15 (p=0.147), at the end of treatment analysis (p=0.245), or after 4 weeks (p=0.154). Neither medication resulted in any abnormal laboratory values, including plasma cortisol levels, over the 12-week safety study period. Both medications were well tolerated.

fluticasone propionate (Cutivate) and hydrocortisone butyrate (Locoid)

In a randomized, double-blind, parallel-group study involving 120 patients, the safety and tolerability of fluticasone propionate 0.05% cream and hydrocortisone butyrate 0.1% cream in the treatment of moderate to severe eczema were compared.[233] Fluticasone propionate was found to be similar in efficacy to hydrocortisone butyrate after 4 weeks. One hydrocortisone butyrate patient's eczema was severely exacerbated by drug therapy over the 12-week safety study, but the drugs were otherwise well tolerated. Plasma cortisol monitoring revealed minimal HPA axis suppression.

The efficacy and safety of fluticasone propionate 0.005% ointment and hydrocortisone butyrate 0.1% ointment twice daily were compared in 113 adult patients with moderate to severe psoriasis in a double-blind, randomized, parallel study.[234] Efficacy assessments were made at weekly intervals for up to 4 weeks. Fluticasone propionate was found to be therapeutically superior to hydrocortisone butyrate, as well as safe and well tolerated. Its onset of action was rapid, and no systemic adverse effects occurred.

halobetasol propionate (Ultravate) and betamethasone dipropionate (Diprolene)

In a double-blind, parallel-group, comparative trial, 104 patients with severe, localized plaque psoriasis were given halobetasol propionate 0.05% ointment or betamethasone dipropionate 0.05% ointment.[235] Halobetasol dipropionate demonstrated an 88.7% success rate assessed as "healed" or "marked improvement" compared to 78.5% for betamethasone dipropionate ointment. Healing was observed within 24 days of the start of treatment in 40% and 25% of the patients who received halobetasol propionate and betamethasone dipropionate ointments, respectively. Tolerability was acceptable for both agents after 4 weeks of treatment. Patients preferred halobetasol propionate ointment over betamethasone dipropionate ointment based on cosmetic acceptability and ease of application.

halobetasol propionate (Ultravate), clobetasol dipropionate (Cormax, Temovate), and betamethasone dipropionate (Diprolene)

In 2 double-blind, parallel-group, multicenter trials, halobetasol propionate 0.05% cream was compared with clobetasol propionate 0.05% cream and betamethasone dipropionate 0.05% cream in 264 patients with acute severe exacerbations of atopic dermatitis.[236] The efficacy of halobetasol propionate and betamethasone dipropionate was similar with regard to the success rate, as indicated by ratings of "healed" and "marked improvement" (88 versus 90%, respectively) and by an onset of therapeutic effect within 3 days of the start of treatment (40 versus 39%). The efficacy of halobetasol propionate and clobetasol propionate was also similar with regard to success rates (89 versus 93%, respectively) and an onset of therapeutic effect within 3 days of the start of treatment (41 versus 38%). Dryness of the skin and itching at the site of application were the reported adverse effects, but the creams were all well tolerated.

halobetasol propionate (Ultravate) and betamethasone valerate (Beta-Val)

In a double-blind, parallel-group comparative trial, 84 patients with severe, localized plaque psoriasis were given halobetasol propionate 0.05% ointment or betamethasone valerate 0.1% ointment.[237] Halobetasol propionate proved significantly superior to betamethasone valerate with respect to the success rate, as indicated by ratings of "healed" or "marked improvement" (88.1 versus 64.3%; p=0.02). The therapeutic effect was observed within 5 days of the initiation of treatment in 76 and 67% of the patients treated with halobetasol propionate and betamethasone valerate, respectively. Both ointments were well tolerated.

hydrocortisone butyrate (Locoid), fluticasone dipropionate (Cutivate), prednicarbate (Dermatop), and mometasone furoate (Elocon)

A randomized, double-blind clinical trial involving 89 subjects with atopic dermatitis compared the safety, efficacy, and cosmetic acceptability of hydrocortisone butyrate 0.1% cream, fluticasone propionate 0.05% cream, prednicarbate 0.1% cream, and mometasone furoate 0.1% cream.[238] Treatments were self-administered twice daily for 2 weeks. Investigator ratings of signs and the patient ratings of signs and symptoms indicated comparable efficacy of all 4 treatments.

SUMMARY

Topical corticosteroids are effective in the treatment of dermatoses. Clinical data suggest that the efficacy of the topical corticosteroids is relative to their potency, but individual agents within a potency category are not distinguishable from each other. Once the disease is under control, it may be possible to decrease the frequency of application of these agents in order to avoid long-term adverse effects.

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